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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,720	07/18/2005	David John Pritchard	ABL-011.SP US	6344
7590 Leon R Yankwich Yankwich & Associates 201 Broadway Cambridge, MA 02139		10/03/2007	EXAMINER COOK, LISA V	
			ART UNIT 1641	PAPER NUMBER
			MAIL DATE 10/03/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/539,720	<b>Applicant(s)</b> PRITCHARD, DAVID JOHN	
	<b>Examiner</b> Lisa V. Cook	<b>Art Unit</b> 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-13, 17, 22, 26-28, 30, 33-39, 43-44, 52, 57-70, 75, 77, 79-83, 88, 90-91 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Continuation of Disposition of Claims: Claims pending in the application are 1-13,17,22,26-28,30,33-39,43,44,52,57-70,75,77,79-83,88,90 and 91.

*Oliver Cook*  
9/9/07

**DETAILED ACTION*****Election/Restrictions***

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1. To have a general inventive concept under PCT rule 13.1, the inventions need to be linked by a special technical feature. The special technical feature that appears to link claims 1-13, 17, 22, 26-28, 30, 33-39, 43-44, 52, 57-70, 75, 77, 79-83, 88, and 90-91 is the measurement and differentiation of various forms of factor XIIa (FXIIa). The claims are also directed to the utility of the factor XIIa measurement in disease assessment. However, factor XIIa detection and differentiation has been taught by the prior art. For example, the reference to Esnouf et al. (Thromb Haemost 2000, Vol.83, pages 874-881) discloses methods for detecting  $\beta$ -factor XIIa and  $\alpha$ -factor XIIa with a monoclonal antibody designated mAb 2/215. See abstract. The procedures distinguish  $\alpha$ -factor XIIa from the " $\alpha$ -factor XIIa:C1-INH complex" (other forms of factor XIIa). See page 877 – Results.

With respect to factor XIIa's use in disease, it is noted that both Dick et al. (Haemostasis, May 2000, Vol.30, No.1-2, page 92 – Abstract Only) and Kariyawasam et al. (Journal of Hypertension, 2000, Vol.18, No.Suppl.4 pages S24-S25 – Abstract Only) teach factor XIIa measurements in renal and cardiovascular disorders.

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Therefore the technical feature recited in claims 1-13, 17, 22, 26-28, 30, 33-39, 43-44, 52, 57-70, 75, 77, 79-83, 88, and 90-91 is not a contribution over the prior art. Accordingly the groups set forth below are not so linked as to form a single general concept under PCT Rule 13.1.

2. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- A. Group **I**, claim(s) 1-13, 17, 22, 26-28, 30, 33-39, 43-44, and 52, are drawn to a method of measuring forms of factor XIIa, classified in class 435, subclass 7.1, for example. (A first method/process that measures/utilizes the special technical feature).
- B. Group **II**, claims 1 and 57-69, are directed to a method of measuring forms of factor XIIa in subjects with a disease or disorder, classified in class 424, subclass 146.1 and classified in class 435, subclass 13, for example. (A second method detecting/employing the special technical feature).
- C. Group **III**, claims 70-91, are directed to methods and databases for monitoring diagnosing a disease or disorder via sample comparison to known subject data, classified in class 436 subclass 501, for example. (A third method measuring/utilizing the special technical feature).

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3. The inventions listed as Groups A through C do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Under PCT rules Applicant is entitled to an examination of one of the combination groupings: (1) a product, a method of using said product and a method of producing said product. The instant claims are directed to multiple methods. Accordingly, Applicant must select one for further prosecution.

4. Because these inventions are distinct for the reasons given above, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group A through C is not totally inclusive, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

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Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

7. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO fax center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (571) 272-0823.

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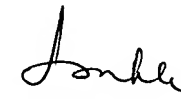
Any inquiry of a general nature or relating to the status of this application should be directed to the Group TC 1600 whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

 9/19/07

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 09/28/07  
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